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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/423,194	04/18/1995	DAN L. EATON	P0871P4D2	8105

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
05/12/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/423,194	EATON ET AL.	
	Examiner	Art Unit	
	LORRAINE SPECTOR	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,6,17 and 38-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,17 and 38-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

All interference proceedings having been terminated, prosecution is reopened in this case.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6 and 38-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 13-15, and 36 of U.S. Patent Application No. 08/223263.

The claims are coextensive, and the claims of the copending application would anticipate the current claims, if said claims were prior art. Accordingly, a finding of obviousness type double patenting is proper.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 2, 6 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 13-15, and 36 of U.S. Patent Application No. 08/223263 in view of Curtis et al. U.S. Patent Number 5,073,627, and Lin, U.S. Patent number 5,441,868.

Curtis et al. teach chimeric proteins in which IL-3 is fused to GM-CSF. The particular proteins were chosen for the fusion because they "have considerable overlap in their broad range of biological activities" (column 1, lines 27-29), specifically that they are both hematopoietic proteins. Curtis et al. do not teach a fusion of IL-3 to thrombopoietin, a.k.a. mpl ligand.

Lin et al. teaches recombinant production of erythropoietin, which is disclosed as being a hematopoietic protein.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to substitute mpl ligand as taught by the provisionally rejected claims and optionally EPO as taught by Lin in the fusion protein of Curtis et al., to obtain a bifunctional hematopoietic protein. The ordinary artisan would have been motivated to do so in view of Curtis' teachings that it is desirable to combine such activities, and would have expected the resultant fusion protein to be at least as effective as the two cytokines administered together as a composition, rather than a fusion protein.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 6 and 38-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 13-15 and 36 of U.S. Patent Application No. 08/374540.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The claims are coextensive, and the claims of the copending application would anticipate the current claims, if said claims were prior art. Accordingly, a finding of obviousness type double patenting is proper.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 2, 6 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6-8, 13-15, and 36 of U.S. Patent Application No. 08/374540 in view of Curtis et al. U.S. Patent Number 5,073,627, and Lin, U.S. Patent number 5,441,868 for reasons cited above.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 6 and 38-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 28 and 32-42 of U.S. Patent Application No. 08/422194.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. Accordingly, a finding of obviousness type double patenting is proper.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 2, 6 and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 28 and 32-42 of U.S. Patent

Application No. 08/422194. in view of Curtis et al. U.S. Patent Number 5,073,627, and Lin, U.S. Patent number 5,441,868 for reasons cited above.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 2, 6, 17 and 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 6, 8, 12-14, 34, 36 and 37 of U.S. Patent Application No. 08/425016.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. Accordingly, a finding of obviousness type double patenting is proper.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 2, 6, 17 and 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 34, 38-40 and 44-46 of U.S. Patent Application No. 08/425095.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. Accordingly, a finding of obviousness type double patenting is proper.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1, 2, 6 and 38-43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, and 24 of U.S. Patent Application No. 08/429365.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. With respect to claim 41, the person of ordinary skill in the art would recognize this as being necessary for recombinant production in *E. coli* or other prokaryotes, which would be necessary to produce unglycosylated protein. Accordingly, a finding of obviousness type double patenting is proper.

Claims 1, 2, 6, 17 and 38-45 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 24 and 28-31 of U.S. Patent Application No. 08/430018.

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. Accordingly, a finding of obviousness type double patenting is proper.

Claims 2, 6, 17, 41, 42 and 43 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-18 and 41-48 of U.S. Patent Application No. 08/433098 in view of (U.S. Patent Number 4,002,531) and Shadle et al. (U.S. Patent Number 4,847,325).

Although the conflicting claims are not identical, they are not patentably distinct from each other because: The claims are coextensive, and the claims of each application would, if prior art, anticipate the claims of the other. With respect to claims 41 and 42, the person of ordinary skill in the art would recognize this as being necessary for recombinant production in *E. coli* or other prokaryotes, which would be necessary to produce unglycosylated protein. With respect to claim 43, Pegylation of proteins (attachment of polyethylene glycol) for the purpose of increasing circulating half life is well known in the art, as evidenced by Royer (U.S. Patent Number 4,002,531) and Shadle et al. (U.S. Patent Number 4,847,325). For example, Royer teaches a method for monopegylation of enzymes to be used as pharmaceuticals, by reductive alkylation.

Shadle et al. disclose the site specific attachment of water soluble polymers to colony stimulating factor-1 (CSF-1). They report that such modification increases the circulating half-life and immunogenicity of the altered protein. At column 2 beginning at line 27, Shadle et al. teach the general desirability of modifying proteins of less than 70 kD to increase their circulating half-life, for example by addition of PEG to the proteins. The paragraph beginning on line 45 of column 4 recites preferred polymers of the invention, which include mPEG, and states specific linkages which may be made to the protein moiety.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the mpl ligand by attachment of PEG as taught by Royer and Shadle et al. One of ordinary skill in the art would have been motivated to do so to attain the known and expected advantages of pegylation, including increased serum half-life of the resulting modified protein. Accordingly, a finding of obviousness type double patenting is proper.

In the response filed 1/7/97, applicants stated that conflicting claims would be cancelled and/or a terminal disclaimer filed as necessary at the time a patent is ready to be issued. As there are no other pending rejections, and all interference issues have been resolved, the instant rejection must be fully responded to, and will not be further held in abeyance.

Further, 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday from 8:00 A.M. to 4:30 P.M. Eastern Time, and Tuesday through Friday, 8:00 A.M. to 2:00 P.M. Eastern Time at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Jeffrey Stucker, at telephone number 571-272-0911.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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